Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of the effect of probiotic yogurt mouthwash on salivary pH in orthodontic patient in sari dentistry school clinic

Protocol summary

Summary

This single-blind clinical trial aims to investigate the effect of probiotic yogurt mouthwash on salivary pH of 40 patients 14-17 years old with both jaws fixed orthodontic appliances. Exclusion criteria includes tooth decay, systemic and gum diseases, the use of steroids and other drugs, smoking and pregnancy. Patients are randomly divided into two groups with table of random numbers. Yogurts are given in similar packages to the patients. During the first period, patients in both groups will not use yogurt for a week. The intervention group receives 20 mL probiotic yogurt (20.000.000 colony/gram Lactobacillus acidophilus and Bifidobacterium lactis) and the control groups receives 20 mL nonprobiotic yogurt after brushing and flossing 2 times daily for 2 weeks for one minute mouthwash, and then avoid mouth washing, eating and drinking for one hour and then wash their mouth. The third period is 2 weeks rest and the patients avoid the consumption of yogurt. In the fourth period, patients in the intervention group receive nonprobiotic yogurt and the control group patients receive probiotic yogurt twice daily for 2 weeks. At the beginning and end of 2nd and 4th period, salivary pH of all patients are measured by labtron ph meter made by Labtron co. Iran. At 10-11 am, unstimulated saliva samples are collected. pH 5 to 5.8 is very acidic, 6 to 6.6 relatively acidic and pH of 6.8 to 7.8 indicates healthy saliva.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040533236N1**
Registration date: **2017-07-25, 1396/05/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-25, 1396/05/03

Registrant information

Name

Nafiseh Zarenejad

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology of Mazandaran University of Medical Sciences

Expected recruitment start date

2016-12-20, 1395/09/30

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of probiotic yogurt mouthwash on salivary pH in orthodontic patient in sari dentistry school clinic

Public title

The effect of probiotic yogurt mouthwash on salivary pH

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age 14-17 years; fixed orthodontic treatment of jaw distance of at least 3 months of treatment Exclusion criteria: Dental decay; systemic diseases; Any disease of the gums and teeth; Systemic corticosteroid and other medications including antibiotics; Chlorhexidine mouthwash; Xylitol gum chewing during the past 4 weeks; smoking; Pregnancy; OCP

Age
From **14 years** old to **17 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences

Street address
Vice Chancellor for Research and Technology, Moallem square, Sari, Iran

City
Sari

Postal code
4815838447

Approval date
2016-10-25, 1395/08/04

Ethics committee reference number
IR.MAZUMS.REC.95.2122

Health conditions studied

1

Description of health condition studied
Fixed orthodontic for teeth

ICD-10 code
Z46.4

ICD-10 code description
Fitting and adjustment of orthodontic device

Primary outcomes

1

Description
Salivary pH

Timepoint
Start of treatment, at the end of 1st, 2nd, 3rd and 4th course

Method of measurement
pH meter

Secondary outcomes

empty

Intervention groups

1

Description
The control group receives 20 mL nonprobiotic yogurt mouthwash twice daily for 2 weeks.

Category
Placebo

2

Description
The intervention group receives 20 mL probiotic yogurt (20.000.000 colony/gram Lactobacillus acidophilus and Bifidobacterium lactis) after brushing and flossing 2 times daily for 2 weeks for one minute mouthwash

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Mazandaran University of Medical Sciences

Full name of responsible person
Nafiseh Zarenejad

Street address
Next to Tooba Clinic, Faculty of Dentistry, Sari

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person
Ahmadali Enayati
Street address
Vice chancellor for research of Mazandaran University of Medical Sciences, Moallem Square, Sari
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty